

Remarks

Claims 1 to 31 are pending in this application with claims 1, 2, 3, 6, 9, 10, 14, 15, 16, 18, 20, 21, 23, 24, 25, 26 being independent claims. The restriction requirement set forth ten (10) groups of claims for restriction purposes stating that the claims constitute patentably distinct inventions as they are not capable of use together or they have different modes of operation, different functions or different effects. The Applicants respectfully traverse the restriction requirements. Pursuant to 37 CFR § 1.143, Applicants request that the requirement be modified such that the claims of at least Groups I, II and III are considered together.

Response to the requirement of Election

In order to comply with the requirement that a single group of claims be elected for examination, the Applicants have provisionally elected, with traverse, Group I (claims 1, 6 to 8 and 29 to 31) for examination. The Applicants respectfully request that the Examiner modifies the restriction in view of the following remarks.

The Examiner has stated that if the identified inventions as claimed do not overlap in scope, i.e. are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect, then the identified inventions are distinct.

In the instant case, the Examiner considers the methods of Groups I, II and III to be distinct, each from the other because each method is directed to a distinct goal or a materially distinct step, is capable of separate use and employs particulars not commonly shared. Hence, the Examiner considers the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination. Moreover, the Examiner considers Group III to be directed to identifying a gene comprising contacting test nematodes that comprise at least one mutation in the *clk-1* gene with a nucleic acid that reduces the level of expression of a nematode gene. The Examiner considers Group III to be distinct from the methods of Groups I and II because it does not require the mutagenesis step of Group II, and because the nucleic acid of Group III, that may be antisense molecule is not required for the method of Group I.

The Applicants respectfully contest the Examiner's contention that the invention of Group III does not require the mutagenesis step of Group II and submit that test nematodes used in claims of Groups II and III are the same. The Applicants also submit that

the same phenotype is measured on these test nematodes towards identifying new genes involved in **the modulation of levels of lipids and lipoproteins**. Furthermore, the Applicants submit that contrary to the contention of the Examiner that the claims of Group II and Group III do not overlap in scope and have different effects, it is clear for a person skilled in the art that claim 2 (Group II) and claim 3 (Group III) are both directed to a gene **that modulates the level of a lipid or lipoprotein in nematodes**. Hence, **the claims are technically linked by the effect of identifying and further isolating a gene that modulates the level of a lipid or lipoprotein in nematodes**. The Applicants submit that the claims of Groups II and III should be considered together and be considered as one group.

In view of the above, the Applicants also submit that Groups I, II and III as identified by the Examiner are directed to related processes and are not distinct since they do overlap in scope. The Applicants have demonstrated above that Groups II and III should be combined in one group. Similarly, the Applicants consider that claims of Group I, should also be considered with claims of Groups II and III since it is clear for a person skilled in the art that claim 1 is directed to a method for identifying a compound that **modulates the level of a lipid or lipoprotein**. Hence, it is clear for a person skilled in the art that all three methods are used to identify **modulators (compounds or genes) of levels of lipids or lipoproteins**. Furthermore, referring to the specification on pages 56 to 57, particularly paragraph 5.3.2.1 where candidate agents and compounds are well-described, it is understood by a person skilled in the art that "compounds" can be nucleic acid molecules, such as the ones claimed in claims of Groups II and III. Hence, the Applicants submit that claims of Groups II and III can be construed as specific embodiments of claim 1. It is thus demonstrated that a special technical feature links the claims of Groups I, II and III, i.e. the identification of a compound that **modulates the level of lipids or lipoproteins**. Hence, Groups I, II and III have the same effects and are not distinct. The Applicants have thus demonstrated that unity of invention between Groups of claims I, II and III does exist.

In view of the above comments and arguments, the Examiner is respectfully requested to reconsider the restriction requirement and consider claims of Groups I, II and III as parts of the same invention for examination on merit.

In response to the requirement to choose one specific dsc/DSC, the Applicants provisionally elect the dsc-4 gene and DSC-4 protein, with traverse. However, the Applicants submit that both dsc/DSC-3 and dsc/DSC-4 are **modulators of lipids and lipoprotein levels (MOLL)**. In this regard, the Examiner is referred to the specification on page 25, line 10 and page 30 line 27. Moreover, the Applicants submit that mutations in dsc-3 or dsc-4 are both

suppressors of *clk-1* mutations in *C. elegans* (see specification page 18, lines 23-24 and page 19, line 27). Hence, it is clear that the sequences are linked by the same technical feature.

The Applicants submit that MPEP 803.4 clearly indicates that "Normally ten sequences constitute a reasonable number for examination purposes". Applicants thus submit that there is no undue burden on the Office to search these sequences together. Applicants therefore respectfully request that this requirement be withdrawn.

Response to the other requirements

In response to the requirement that Applicants select a single species among the nematode associated phenotypes related to the length of defecation cycle, the rate of germ line versus soma development, the rate of embryonic and post embryonic development, expression profile of one or more gene and the distribution of a lipid or lipoprotein, the Applicants provisionally elect the length of defecation cycle, with traverse. The Applicants respectfully submit that these phenotypes are not patentably distinct species of the claimed inventions since it is clear from the description on page 55, lines 20 to 27 in paragraph 5.3.2 that all the phenotypes recited are associated with the lipid or lipoprotein modulation. Hence, it is clear that the phenotypes are technically related. The Examiner is thus respectfully requested to reconsider his request to elect one phenotype.

Further, the Applicant has noted the Examiner's request to choose a specific nucleic acid as recited in claim 4 from Group III. In response to this requirement, the Applicants provisionally elect the antisense nucleic acid, with traverse. The Applicants submit that antisense nucleic acid and double-stranded RNA do have the same effect of reducing specifically the level of expression of a nematode gene. The Applicants further submit that both molecules will be used for hybridization with a complementary strand of a nucleic acid involved in the **modulation of lipids and lipoproteins levels**. Hence, in this respect, they are technically linked. The Applicants thus respectfully request the Examiner to reconsider his request.

Applicants respectfully request that the Examiner reconsider the restriction requirement in view of the remarks set forth above. Applicants request that the Examiner considers the claims of at least Groups I, II and III together as all of these groups relate to the identification of compounds **modulating lipids and lipoproteins levels**, and therefore would not constitute an undue burden for the Examiner to search together. Furthermore, Applicants further request that the phenotypes of nematodes, namely length of defecation cycle, rate of germ line development relative to rate of soma development, rate of embryonic development

and rate of post embryonic development be considered together as all are correlated with lipid or lipoprotein level. Finally, the Examiner is requested to consider antisense nucleic acid and the double stranded RNA molecule of claim 4 together as those are clearly related to each other as suggested from the specification.

Should the species restriction be maintained, the Applicants, upon the allowance of a generic claim, will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

The Applicants retain the right to petition from the restriction requirement under 37 U.S.C. § 1.144.

CONCLUSION

Applicants respectfully request that the present remarks be made of record in the instant application. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

Date: October 23, 2006

Laura A Courzzi 30,742
Laura A Courzzi (Reg. No.)

By: T. Christopher Tsang 40,258
T. Christopher Tsang (Reg. No.)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939